

and, Section 502 (f) (1) and (2), the repackaged tablets failed to bear labeling containing adequate directions for use and adequate warnings against use in those pathological conditions where their use may be dangerous to health, and against unsafe dosage and methods and duration of administration, in such manner and form, as are necessary for the protection of users.

DISPOSITION: June 12, 1953. The defendants having entered pleas of nolo contendere, the court imposed a fine of \$50 against Defendant Douglas and \$100 against Defendant Evans, plus costs.

**4146. Misbranding of Glando tablets. U. S. v. 1 Bottle, etc. (F. D. C. No. 34904. Sample No. 57738-L.)**

**LABEL FILED:** March 20, 1953, Eastern District of Virginia.

**ALLEGED SHIPMENT:** On or about December 31, 1952, and February 23, 1953, from Baltimore, Md.

**PRODUCT:** 1 bottle, containing 6,000 tablets, and 30 boxes, each box containing 16 tablets, of *Glando tablets* at Norfolk, Va., in the possession of the Medical Products Co., together with a number of loose labels.

**RESULTS OF INVESTIGATION:** The above-mentioned tablets had been shipped in interstate commerce in bulk containers, and after their receipt by the Medical Products Co., a number of the tablets were repackaged by that company into boxes labeled as indicated below.

**LABEL, IN PART:** (Box) "Glando Builds Up Vitality, Health And Strength Medical Products Company Norfolk, Va. Directions—One to two tablets after meals and bedtime \* \* \* Recommended for loss of manhood, debility, lack of vitality, loss of appetite, weakness, etc."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), certain statements on the box labels of the tablets were false and misleading. The statements represented and suggested that the article was an adequate and effective treatment for loss of manhood, debility, lack of vitality, loss of appetite, and weakness, and for building up health and strength. The article was not an adequate and effective treatment for such conditions and purposes.

Further misbranding, Section 502 (e) (2), the box label of the article failed to declare the presence and proportion of strychnine contained in the tablets and the presence of the active ingredients, cantharides and zinc phosphide; and, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, and against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users since its labeling failed to bear warnings against use of this article, which contained strychnine, cantharides, and zinc phosphide.

The article was alleged to be misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: May 20, 1953. Default decree of condemnation and destruction.

**4147. Misbranding of Niagara device. U. S. v. 13 Devices, etc. (F. D. C. No. 34938. Sample Nos. 20731-L, 48670-L.)**

**LABEL FILED:** April 8, 1953, Southern District of Iowa.

**ALLEGED SHIPMENT:** On or about January 9 and February 20, 1953, by Niamco, Inc., from Dallas, Tex.

**PRODUCT:** 13 *Niagara Hand Unit devices* and 7 all purpose *Niagara Portable devices* at Des Moines, Iowa, in the possession of the Niagara Massage Units Co., together with an accompanying placard entitled "Poor Circulation."

Examination showed that the devices were vibrators. The hand unit device was so designed as to adapt it to be held in the hand while being applied to any part of the body, and the all purpose device was designed for sitting or leaning upon or for resting the feet upon.

**RESULTS OF INVESTIGATION:** The above-mentioned placard was posted on the wall of the consignee's office, where the devices were demonstrated to potential purchasers. In addition, the devices were represented orally to be effective in treating the diseases and conditions hereinafter mentioned. Such representations were made by a saleslady for the consignee.

**LABEL, IN PART:** "Niagara of Adamsville, Pennsylvania Hand Unit [or "All Purpose Portable Model No. 5"]."

**NATURE OF CHARGE:** Misbranding, Section 502 (a), the placard accompanying the devices contained statements which represented and suggested that the devices were effective for circulatory disorders, which statements were false and misleading since the devices were not effective for circulatory disorders.

Further misbranding, Section 502 (f) (1), the labeling of the devices failed to bear adequate directions for use for the purposes for which they were intended, namely, for treating disorders of the heart, kidneys, circulation, gallbladder, colon, rectum, respiratory tract, joints, and nervous system; and for cancer, osteomyelitis, constipation, ulcers of the colon, multiple sclerosis, and asthma.

The devices were misbranded in the above respects while held for sale after shipment in interstate commerce.

**DISPOSITION:** June 26, 1953. John L. Naughton, trading as the Niagara Massage Units Co., Des Moines, Iowa, claimant, having consented to the entry of a decree, judgment of condemnation was entered and the court ordered that the devices be released under bond for relabeling under the supervision of the Department of Health, Education, and Welfare.

#### DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS\*

**4148. Adulteration of chorionic gonadotropin. U. S. v. 944 Vials \* \* \*. (F. D. C. No. 34945. Sample Nos. 38061-L, 38063-L.)**

**LABEL FILED:** April 13, 1953, Southern District of New York.

**ALLEGED SHIPMENT:** On or about August 29, 1952, by Ormonoterapia, s. r. l., from Milan, Italy.

**PRODUCT:** 944 vials of *chorionic gonadotropin* in boxes at New York, N. Y.

**LABEL, IN PART:** (Box) "Corionic Gonadotropin lyophilized in final containers box of 50 vials."

**NATURE OF CHARGE:** Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported to possess since the article was intended for injection into man and should be sterile, whereas it was contaminated with living micro-organisms.

**DISPOSITION:** May 6, 1953. Default decree of condemnation and destruction.

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\*See also No. 4160 (veterinary preparation).